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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/499,423 | 07/07/1995 | CAREY V. CAMPBELL | MP/84 | 2478 |

7590 05/17/2004
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EXAMINER

PELLEGRINO, BRIAN E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3738

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/499,423

Applicant(s)

CAMPBELL ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-33,35,42-44,46-66,74-77,82-88 and 91-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-33,35,42-44,46-66,74-77,82-88 and 91-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/23/04 has been entered.

Claim Objections

Claims 1,3-7,9-32 are objected to because of the following informalities: Claim 1 recites the limitation "said **first** circumference" in line 5 of the claim. It should be mentioned previously so it is clear what circumference is being described. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-7,9-17, 19-31,33,35,42-44,46-66,74-77,82-88,91-97 are rejected under 35 U. S.C. 102(e) as being anticipated by Shannon et al. (5641373). Shannon et al. disclose a tube base made of porous PTFE and is covered by one or more layers of porous PTFE material, col. 2, lines 21-24. Shannon also discloses the device has a

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microstructure of nodes and fibrils, col. 1, lines 19-30. The wall thickness has a measurement of about 0.1 mm and less than 0.25mm, see col. 16, lines 57,58. The graft can be anchored via a stent, col. 11, lines 8-14 and can also be sutured, line 55. Regarding claims 17 and 31, since the graft is inherently capable of expanding to a second circumference, it is fully capable of having a tapered profile upon expansion in a tapered vessel. The tube or article is fully capable of increasing to at least 100% the first circumference since the device is made of the same materials and has the same thickness, it inherently must possess the same physical properties.

Claims 86-88,91,95-97 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldfarb (6436135). Goldfarb discloses a tube of PTFE (col. 3, lines 40-55) that is fully capable of having its circumference increase with blood pressure application. The prosthesis is for use as a vascular graft, col. 1, lines 3-5. The graft is fully capable of being adapted for" use as an endoluminal graft. The tube has a wall thickness about 0.25mm, col. 7, lines 9, 10. Regarding claim 91, the examiner asserts that the claimed physical properties (in this case, recoil) are present in the prior art material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art. Since the graft is made of the same materials and has the same thickness, it inherently must possess the same physical properties.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon et al. '373 in view of Hughes et al. (4728328). Shannon et al. is explained supra. However, Shannon does not disclose a tube that is branched with three ends. Hughes et al. teach a tubular prosthesis that is branched with three ends, Fig. 12. It would have been obvious to one of ordinary skill in the art to use the branched tubular form as taught by Hughes with the prosthesis of Shannon in a vessel such as the trachea requiring replacement to the two bronchi.

Claims 92-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldfarb '135. Goldfarb is explained supra. However, Goldfarb fails to disclose the minimal recoil is 14,10 or 7% or less. It would have been an obvious matter of design choice to modify the minimum recoil, since applicant has not disclosed that using any particular percentage provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the recoil taught by Goldfarb or the claimed 14,10 or 7% or less in claim(s) 92-94 because both tubes perform the same function of providing a graft to permit blood flow through them.

Response to Arguments

Applicant's arguments filed 2/23/04 have been fully considered but they are not persuasive. Because the Patent & Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed invention or subject matter is unobvious over the Goldfarb or Shannon tubes, the examiner properly shifts the burden to Applicants to show that unobvious differences exist, *Ex parte Phillips*, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93). The claimed material is the same material as what is disclosed in the Goldfarb and Shannon references. Thus these tubes must inherently possess the same functional properties as in the claims.

Please note that the features of an apparatus may be recited either structurally or functionally and when claims are directed to an apparatus, they must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a *device is*, not what a *device does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

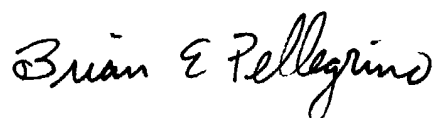
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 703-306-5899. The examiner can normally be reached on Monday-Thursday from 7:30am to 5pm. The examiner can also be reached on alternate Fridays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

Brian E. Pellegrino

A handwritten signature in cursive script that reads "Brian E. Pellegrino". The signature is written in dark ink and is positioned below the printed name.